

# The Role Of the Quality Manager in Stem Cell Transplantation at the University Hospitals of Leicester

by Sarah Ward

# My Background

- 20 years experience as a Biomedical Scientist in Haematology/ Blood Transfusion
- Head hunted by Transplant Director!!
- Started as Stem Cell Lab Quality Manager – June 2009
- Trust Re-organisation - 2012 resulted in my role changing to the UHL/NGH Transplant Programme Quality Manager (January 2014)

# UHL/NGH Transplant Programme

- Main site at Leicester Royal Infirmary (LRI)
- Autologous transplants only at Northampton General Hospital (NGH)
- Adult Autologous & Allogeneic Programme (Sibling and unrelated)
- 85 transplants per year (75 LRI, 10 NGH)
- 120-140 apheresis collections per year



# Role as SCL Quality Manager

- Document control –Q Pulse
- Audits
- Investigate & follow-up incidents, variances (unplanned deviations), adverse infusion events, etc.
- Concessions (planned deviations)
- Designated Person with the HTA- reports Serious Adverse Events and reactions using the online reporting system

# Role as SCL Quality Manager(2)

- Monitor transplant outcomes and investigate anomalies- Engraftment
- COSHH & Risk Assessments
- Review SLA /TPA /TA with internal and external organisations
- Validations
- Authorise cell release for infusion, disposal or research

# SCOPE OF NEW ROLE





# New Role

## -additional responsibilities? (1)

- Responsible for quality of stem cell products through collection – processing – storage – infusion – disposal
- Ensuring we achieve and maintain all required accreditation- JACIE & HTA  
MHRA- not currently required

# New Challenges

- Document Control
  - SCL- annual reviews spread evenly over year
  - Clinical- 2 year review;  
all in June or November of second year  
(150 documents)!!
- Audit Plan
  - SCL -3 year audit plan, most audits completed within set month
    - critical procedures audited every 6 months by me!
  - Clinical- more ad hoc audit plan!!



# New Challenges (2)

- Staff Engagement
  - SCL- QMS totally embedded within working practices
  - Clinical
    - QMS regarded as an alien concept!
    - Creates lots of work
    - Is Bureaucratic!

# Advantages

- More coordinated programme
  - Quarterly Quality Standards/Annual Review Meetings
  - Increased communication with Transplant Director
  - Improved communication with NGH Quality Manager
- Financial- just my wage!!
- Incident Reporting- improved product/ patient related reporting

# Role Development

- Identify a Quality Lead for each area
- Staff Training – Transplant Staff Education Day
- Potential Introduction of Information Management System for Programme
- Encourage increased involvement of apheresis staff in transplant planning
- Increase the number of trained auditors



Thank you for your kind  
attention

Any Questions?